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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,835	10/28/2002	Kouichi Ishikawa	112387	5261

7590

11/17/2004

Oliff & Berridge
PO Box 19928
Alexandria, VA 22320

EXAMINER

MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 11/17/2004

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,835

Applicant(s)

ISHIKAWA ET AL.

Examiner

Patricia C. Mallari

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2004.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 21-34 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 1 and 2 is/are allowed.
6) ☒ Claim(s) 3-13 and 21-32 is/are rejected.
7) ☒ Claim(s) 33 and 34 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 28 October 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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This is a non-final Office action. The new grounds of rejection based on US Patent No. 6,221,026 to Phillips are presented.

Claim Objections

Applicant is advised that should claim 29 be found allowable, claim 31 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3-5, 10, 11, 21-23, 28, 29, 31 and 32 are rejected under 35 U.S.C. 102(e) as being unpatentable over US Patent No. 6,221,026 to Phillips (Phillips '026). Phillips '026 teaches a breath analyzing apparatus for testing for disease comprising a breath collecting section for introducing breath to be analyzed (col. 10, lines 41-61 of Phillips '026), a breath analyzing section wherein isopropanol in the breath is quantified by the area under the curve AUC (col. 10, line 64-col. 11, line 21; col. 13, lines 35-39; col. 14,

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lines 47-50; col. 20, line 22 of Phillips '026), and a data processing section which analyzes the quantified result obtained by the breath analyzing section by determining the alveolar gradient of isopropanol (col. 11, lines 19-28; col. 12, line 60-col. 13, line 3; col. 20, line 22 of Phillips '026).

As to the language "for testing for hepatic disease" on lines 1-2 of claim 3 and "for testing for hepatic cirrhosis" on line 1 of claim 21, the applicants should note that this is merely "intended use" language which cannot be relied upon to define over Phillips '026, since the reference teaches all of the claimed elements and their recited relationships. See *Ex parte Masham 2* USPQ 2nd 1647. The apparatus described by Phillips '026 is perfectly capable of being used to test for hepatic cirrhosis or other hepatic disease.

Regarding claims 4, 5, 11, 22, 23, 29, and 31 the breath collecting section consists of a breath collecting means and a breath transfer means (col. 10, lines 41-59 of Phillips '026). With further regard to claims 5 and 23, the breath collecting means is a mouthpiece (col. 10, lines 54-55 of Phillips '026). With further regard to claims 11, 29, and 31 the breath analyzing section comprises a mass spectrometer (col. 10, lines 66-67 of Phillips '026).

Regarding claims 10 and 28, the breath analyzing section comprises a mass spectrometer (col. 10, lines 66-67 of Phillips '026).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-9, 12, 13, 24-27, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips '026, as applied to claims 3-5, 10, 11, 21-23, 28, 29, 31 and 32 and further in view of US Patent No. 5,573,005 to Ueda. Phillips '026 describes using a system having a heated, portable, microprocessor-controlled breath collection apparatus and gas chromatograph but fails to describe the system, particularly the breath collection apparatus in detail. However, Ueda discloses a heated, portable, microprocessor-controlled breath collection apparatus and gas chromatograph for collecting and analyzing expiration from a user (fig. 1; col. 2, line 46-col. 3, line 65; col. 4, lines 11-26 of Ueda). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the system of Ueda as that of Phillips '026 since Phillips '026 teaches using a system comprising a breath collection apparatus and gas chromatograph, and Ueda describes such a system.

Regarding claims 6 and 24, the breath collecting means is a communicating opening for connecting a breath container 12 (fig. 1; col. 5, lines 1-35 of Ueda).

Regarding claims 7-9, 12, 13, 25-27, and 30, the breath transfer means comprises a duct which connects the breath collecting means 4, 6, 8 with the breath analyzing section 14 (fig. 1; col. 5, lines 24-30 of Ueda). With further regard to claims 8 and 26, the breath transfer means further includes a pump means (piston of syringe 12 and motor 22) to send breath to the breath analyzing section (col. 5, lines 17-30 of Ueda). With further regard to claims 9, 13, and 27, the breath collecting means

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includes a mouthpiece 8 (col. 5, lines 1-2 of Ueda), a communicating opening for connecting a breath container 12 (fig. 1 of Ueda), and a valve means 10 which can be switched so that only one of the mouthpiece 8 and the breath container 12 communicates with the breath analyzing section 14 (col. 15, lines 17-30 of Ueda). With further regard to claims 12, 13, and 30 the breath analyzing section comprises a mass spectrometer (col. 10, lines 65-67 of Phillips '026).

Response to Arguments

Applicant's arguments with respect to claims 3-13 and 21-32 have been considered but are moot in view of the new grounds of rejection.

Allowable Subject Matter

Claims 1 and 2 are allowed.

Claims 33 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: With regard to claims 1 and 2, the prior art of record fails to teach or fairly suggest a method of testing for hepatic diseases by quantifying either isopropanol or cyanides in the breath or an apparatus which quantifies isopropanol or cyanides in the breath. US Patent No. 6,248,078 to Risby et al. teaches a method of testing for hepatic diseases (col. 10, lines 33-49 of Risby) wherein breath is collected, (col. 10, line 64-col. 11, line 4; col. 15, line 12 of Risby), at least one volatile organic compound in the breath is quantified (col. 11, lines 5-16; col. 15, lines 12-20; col. 16, lines 49-55 of Risby), and

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the quantified result obtained by the breath analyzing section is analyzed (col. 15, line 13; col. 16, lines 20-25 of Risby). Risby fails to disclose either isopropanol or cyanide as the volatile organic compound to be quantified. While it can be shown that isopropanol (isopropyl alcohol, 2-propanol) is indeed a volatile organic compound (see col. 3, lines 5-7 of US Patent No. 3,730,182 to Boghosian; col. 9, line 65-col. 10, line 3 of US Patent No. 5,087,786 to Nubel et al.; col. 20, line 22 of Phillips '026) the mere showing of isopropanol as a volatile organic compound fails to provide sufficient motivation to quantify particularly isopropanol or cyanide in the method disclosed by Risby et al.

Additionally, US Patent No. 6,221,026 to Phillips discloses a method of collecting breath, quantifying isopropanol in the breath, and analyzing a result thereof (col. 10, lines 42-61; col. 13, lines 27-43; col. 14, lines 47-50; col. 20, line 22 of Phillips) but fails to teach testing for hepatic diseases and analyzing a result of the quantification of isopropanol. Therefore, no prior art teaches a method for testing for hepatic disease wherein isopropanol and/or cyanides are quantified, as claimed by the present application

With regard to claims 33 and 34, the prior art fails to teach or fairly suggest either a method or apparatus wherein cyanides in the breath are quantified.

Conclusion

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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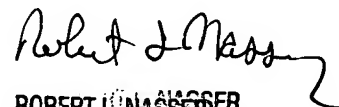
accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Patricia Mallari
Patent Examiner
Art Unit 3736


ROBERT L. NASSER
PRIMARY EXAMINER